DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

25 CFR Ch. V

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS

ACTION: Semiannual Regulatory Agenda

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 require the semiannual issuance of an inventory of rulemaking actions under development throughout the Department, offering for public review summarized information about forthcoming regulatory actions.

FOR FURTHER INFORMATION CONTACT: Wilma Robinson, Deputy Executive Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; (202) 690-5627.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) is the Federal government's lead agency for protecting the health of all Americans and providing essential

human services, especially for those who are least able to help themselves. HHS enhances the health and well-being of Americans by promoting effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

This Agenda presents the rulemaking activities that the Department expects to undertake in the foreseeable future to advance this mission. The Agenda furthers several Departmental goals, including strengthening health care; advancing scientific knowledge and innovation; advancing the health, safety, and well-being of the American people; increasing efficiency, transparency, and accountability of HHS programs; and strengthening the nation's health and human services infrastructure and workforce.

HHS has an agency-wide effort to support the Agenda's purpose of encouraging more effective public participation in the regulatory process. For example, to encourage public participation, we regularly update our regulatory webpage (http://www.HHS.gov/regulations) which includes links to HHS rules currently open for public comment, and also provides a "regulations toolkit" with background information on regulations, the commenting process, how public comments influence the development of a rule, and how the public can provide effective comments. HHS also actively encourages meaningful public participation in its retrospective review of regulations, through a comment form on the HHS retrospective review webpage (http://www.HHS.gov/RetrospectiveReview).

The rulemaking abstracts included in this paper issue of the **Federal Register** cover, as required by the Regulatory Flexibility Act of 1980, those prospective HHS rulemakings likely to have a significant economic impact on a substantial number of small entities. The Department's complete Regulatory Agenda is accessible online at http://www.RegInfo.gov.

NAME: Madhura C. Valverde,

Executive Secretary to the Department.

Office of the Secretary—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
261	Removal of 2 CFR Subsection 376.147 **(Rulemaking Resulting From a Section 610 Review)**	0991–AC08
262	Uniform Administrative Requirements, Costs Principles and Adult Requirements (45 CFR 75) **(Rulemaking Resulting From a Section 610 Review)**	0991–AC09

Office for Civil Rights—Completed Actions

Sequence Number	Title	Regulation Identifier Number
263	Nondiscrimination Under the Patient Protection and Affordable Care Act	0945–AA02

Office of the National Coordinator for Health Information Technology—Completed Actions

Sequence	Title	Regulation Identifier

Number		Number
264	ONC Health IT Certification Program: Enhanced Oversight and Accountability	0955–AA00

Food and Drug Administration—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
265	Over-the-Counter (OTC) Drug Review—Cough/Cold (Antihistamine) Products	0910–AF31
266	Updated Standards for Labeling of Pet Food	0910–AG09
267	Format and Content of Reports Intended To Demonstrate Substantial Equivalence	0910–AG96
268	Radiology Devices; Designation of Special Controls for the Computed Tomography X-Ray System	0910–AH03
269	Mammography Quality Standards Act; Regulatory Amendments **(Reg Plan Seq No. 35)**	0910–AH04
270	Investigational New Drug Application Annual Reporting	0910–AH07
271	Requirements for Tobacco Product Manufacturing Practice	0910–AH22
272	Use of Ozone Depleting Substances **(Section 610 Review)**	0910–AH36

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register.**

Food and Drug Administration—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
273	Postmarketing Safety Reporting Requirements for Human Drug and Biological Products	0910–AA97
274	Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910–AC53
275	Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices	0910–AG48
276	Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products	0910–AG94
277	Food Labeling; Gluten-Free Labeling of Fermented, Hydrolyzed, or Distilled Foods	0910–AH00
278	General and Plastic Surgery Devices: Sunlamp Products	0910–AH14
279	Submission of Food and Drug Administration Import Data in the Automated Commercial Environment **(Section 610 Review)**	0910–AH41

Food and Drug Administration—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number

280	Laser Products; Amendment to Performance Standard	0910–AF87
281	Requirements for the Testing and Reporting of Tobacco Product Constituents, Ingredients, and Additives	0910–AG59
282	Regulations on Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act	0910–AH10
283	Topical Antimicrobial Drug Products for Over-the-Counter Human Use: Final Monograph for Consumer Antiseptic Wash Products	0910–AH40

Food and Drug Administration—Completed Actions

Sequence Number	Title	Regulation Identifier Number
284	Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs	0910–AA49
285	Food Labeling: Revision of the Nutrition and Supplement Facts Labels	0910–AF22
286	Food Labeling: Serving Sizes of Foods That Can Reasonably Be Consumed At One Eating Occasion; Dual-Column Labeling; Updating, Modifying, and Establishing Certain RACCs	0910–AF23
287	Safety and Effectiveness of Consumer Antiseptics; Topical	0910–AF69

	Antimicrobial Drug Products for Over-the-Counter Human Use	
288	Abbreviated New Drug Applications and 505(b)(2) Applications	0910–AF97
289	"Tobacco Products" Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act	0910–AG38
290	Focused Mitigation Strategies To Protect Food Against Intentional Adulteration	0910–AG63

Centers for Medicare & Medicaid Services—Proposed Rule Stage

Sequence Number	Title	Regulation Identifier Number
291	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2018 Rates (CMS-1677-P) **(Section 610 Review)**	0938–AS98
292	CY 2018 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1676-P) **(Section 610 Review)**	0938–AT02
293	CY 2018 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1678-P) **(Section 610 Review) (Reg Plan Seq No. 46)**	0938–AT03

References in boldface appear in The Regulatory Plan in part II of this issue of the **Federal Register.**

Centers for Medicare & Medicaid Services—Final Rule Stage

Sequence Number	Title	Regulation Identifier Number
294	Merit-Based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) in Medicare Fee-for-Service (CMS-5517-FC) **(Section 610 Review)**	0938–AS69
295	CY 2017 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements (CMS-1648-F) **(Section 610 Review)**	0938–AS80
296	CY 2017 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Medicare Part B (CMS-1654-F) **(Section 610 Review)**	0938–AS81
297	CY 2017 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates (CMS-1656-FC) **(Section 610 Review)**	0938–AS82

Centers for Medicare & Medicaid Services—Long-Term Actions

Sequence Number	Title	Regulation Identifier Number
298	Conditions of Participation for Home Health Agencies (CMS-3819-F) **(Rulemaking Resulting From a Section 610 Review)**	0938–AG81
299	Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-F) **(Rulemaking Resulting From a Section 610 Review)**	0938–AS21
300	Imaging Accreditation (CMS-3309-P) **(Section 610 Review)**	0938–AS62
301	Part B Drug Payment Model (CMS-1670-F) **(Section 610 Review)**	0938–AS85

Centers for Medicare & Medicaid Services—Completed Actions

Sequence Number	Title	Regulation Identifier Number
302	Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (CMS-3178-F) **(Section 610 Review)**	0938–AO91
303	Reform of Requirements for Long-Term Care Facilities (CMS-3260-F) **(Rulemaking Resulting From a Section 610 Review)**	0938–AR61
304	Medicare Clinical Diagnostic Laboratory Test Payment System	0938–AS33

	(CMS-1621-F) **(Completion of a Section 610 Review)**	
305	Medicare Shared Savings Program; Accountable Care Organizations (ACOs)—Revised Benchmark Rebasing Methodology (CMS-1644-F) **(Completion of a Section 610 Review)**	0938–AS67
306	Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2017 Rates (CMS-1655-F) **(Completion of a Section 610 Review)**	0938–AS77

Department of Health and Human Services (HHS)	**Final Rule Stage**
Office of the Secretary (OS)	

261. • REMOVAL OF 2 CFR SUBSECTION 376.147 (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 5 U.S.C. 301; 31 U.S.C. 6101

Abstract: HHS is amending its adoption of the Office of the Management and Budget's Nonprocurement Common Rule, found at 2 CFR part 180. This will remove 2 CFR subsection 376.147, which provides information about the scope of HHS OIG exclusions under title XI of the Social Security Act.

Timetable:

Action	**Date**	**FR Cite**

Interim Final Rule	11/00/16	

Regulatory Flexibility Analysis Required: Undetermined

Agency Contact: TiffanI Redding, Program Analyst, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue, SW., Washington, DC 20201

Phone: 202 202–4321

RIN: 0991–AC08

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262. • UNIFORM ADMINISTRATIVE REQUIREMENTS, COSTS PRINCIPLES AND ADULT REQUIREMENTS (45 CFR 75) (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 5 U.S.C. 301

Abstract: This will address the comments of the NPRM to 45 CFR 75 and to include additional provision that are not in conflict with OMB's language, and provide additional guidance regulated community.

Timetable:

Action	Date	FR Cite
Final Action	11/00/16	

Regulatory Flexibility Analysis Required: No

Agency Contact: Quadira Dantro, Federal Assistance Policy Specialist, Department of Health and Human Services, Office of the Secretary, 200 Independence Avenue, SW., Washington, DC 20201

Phone: 202 260–6825

RIN: 0991–AC09

Department of Health and Human Services (HHS)	Completed Actions
Office for Civil Rights (OCR)	

263. NONDISCRIMINATION UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT

Legal Authority: 42 U.S.C. 18116

Abstract: This final rule implements prohibitions against discrimination on the basis of race, color, national origin, sex, age, and disability as provided in section 1557 of the Affordable Care Act. Section 1557 provides protection from discrimination in health programs and activities of covered entities. This section also identifies additional forms of Federal financial assistance to which the section will apply.

Timetable:

Action	Date	FR Cite
NPRM	09/08/15	80 FR 54172
NPRM Comment Period End	11/09/15	
Final Action	05/18/16	81 FR 31376

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Eileen Hanrahan, Senior Civil Rights Analyst, Department of Health and Human Services, Office for Civil Rights, 200 Independence Avenue SW., Washington, DC 20201

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RIN: 0945–AA02

Department of Health and Human Services (HHS)	Completed Actions
Office of the National Coordinator for Health Information Technology (ONC)	

264. ONC HEALTH IT CERTIFICATION PROGRAM: ENHANCED OVERSIGHT AND ACCOUNTABILITY

Legal Authority: sec. 3001(c0(5) of the Public Health Service Act

Abstract: The rulemaking introduces modifications and new requirements under the ONC Health IT Certification Program (''Program''), including provisions related to the Office of the National Coordinator for Health Information Technology (ONC)'s role in the Program. The proposed rule proposes to establish processes for ONC to directly review health IT certified under the Program and take action when necessary, including requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The proposed rule includes processes for ONC to authorize and oversee accredited testing laboratories under the Program. It also includes a provision for the increased transparency and availability of surveillance results.

Timetable:

Action	Date	FR Cite
NPRM	03/02/16	81 FR 11056
NPRM Comment Period End	05/02/16	

Final Action	10/19/16	81 FR 72404
Final Action Effective	12/19/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Michael Lipinski, Policy Analyst, Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Room 729D, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

Phone: 202 690–7151

RIN: 0955–AA00

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Food and Drug Administration (FDA)	

265. OVER–THE–COUNTER (OTC) DRUG REVIEW—COUGH/COLD (ANTIHISTAMINE) PRODUCTS

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371

Abstract: FDA will be proposing a rule to add the common cold indication to certain over-the-counter (OTC) antihistamine active ingredients. This proposed rule is the result of collaboration under the U.S.-Canada Regulatory Cooperation Council (RCC) as part of efforts to reduce unnecessary duplication and differences. This pilot exercise will help determine the feasibility of developing an ongoing mechanism for alignment in review and adoption of OTC drug monograph elements.

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/00	65 FR 51780
Comment Period End	11/24/00	
NPRM (Amendment) (Common Cold)	01/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice Adams–King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AF31

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266. UPDATED STANDARDS FOR LABELING OF PET FOOD

Legal Authority: 21 U.S.C. 343; 21 U.S.C. 371; Pub. L. 110–85, sec 1002(a)(3)

Abstract: FDA is proposing updated standards for the labeling of pet food that include nutritional and ingredient information, as well as style and formatting standards. FDA is taking this action to provide pet owners and animal health professionals more complete and consistent information about the nutrient content and ingredient composition of pet food products.

Timetable:

Action	Date	FR Cite
NPRM	04/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: William Burkholder, Veterinary Medical Officer, Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine, MPN–4, Room 2642, HFV–228, 7519 Standish Place, Rockville, MD 20855

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RIN: 0910–AG09

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267. FORMAT AND CONTENT OF REPORTS INTENDED TO DEMONSTRATE SUBSTANTIAL EQUIVALENCE

Legal Authority: 21 U.S.C. 387e(j); 21 U.S.C. 387j(a); 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 387b; 21 U.S.C 387c; 21 U.S.C. 387i

Abstract: This regulation would establish the format and content of reports intended to demonstrate substantial equivalence. This regulation also would provide information as to how the Agency will review and act on these submissions.

Timetable:

Action	Date	FR Cite
NPRM	11/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Annette L. Marthaler, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG96

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268. RADIOLOGY DEVICES; DESIGNATION OF SPECIAL CONTROLS FOR THE COMPUTED TOMOGRAPHY X–RAY SYSTEM

Legal Authority: 21 U.S.C. 360c

Abstract: The proposed rule would establish special controls for the computed tomography (CT) X-ray system. A CT X- ray system is a diagnostic X-ray imaging system intended to produce cross-sectional images of the body through use of a computer to reconstruct an image from the same axial plane taken at different angles. High doses of ionizing radiation can cause acute (deterministic) effects such as burns, reddening of the skin, cataracts, hair loss, sterility, and, in extremely high doses, radiation poisoning. The design of a CT X-ray system should balance the benefits of the device (i.e., the ability of the device to produce a diagnostic quality image) with the known risks (e.g., exposure to ionizing radiation). FDA is establishing proposed special controls, which are necessary to provide reasonable assurance of the safety and effectiveness of a class II CT X-ray system.

Timetable:

Action	Date	FR Cite

NPRM	08/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Erica Blake–Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH03

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269. MAMMOGRAPHY QUALITY STANDARDS ACT; REGULATORY AMENDMENTS

Regulatory Plan: This entry is Seq. No. 35 in part II of this issue of the **Federal Register.**

RIN: 0910–AH04

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270. INVESTIGATIONAL NEW DRUG APPLICATION ANNUAL REPORTING

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355(i); 21 U.S.C. 371(a); 42 U.S.C. 262(a)

Abstract: This proposed rule would revise the requirements concerning annual reports submitted to investigational new drug applications (INDs) by replacing the current annual reporting requirement with a requirement that is generally consistent with the format, content, and timing of submission of the development safety update report devised by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Timetable:

Action	Date	FR Cite
NPRM	04/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ebla Ali Ibrahim, Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 6302, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH07

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271. REQUIREMENTS FOR TOBACCO PRODUCT MANUFACTURING PRACTICE

Legal Authority: 21 U.S.C. 371; 21 U.S.C. 387b; 21 U.S.C. 387f

Abstract: FDA is proposing requirements that govern the methods used in, and the facilities and controls used for, the pre-production design validation, manufacture, packing, and storage of tobacco products.

Timetable:

Action	Date	FR Cite
ANPRM	03/19/13	78 FR 16824
ANPRM Comment Period End	05/20/13	

NPRM	05/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Darin Achilles, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Document Control Center, Building 71, Room G335, Silver Spring , MD 20993

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RIN: 0910–AH22

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272. USE OF OZONE DEPLETING SUBSTANCES (SECTION 610 REVIEW)

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 335; 21 U.S.C. 342; 21 U.S.C. 346a; 21 U.S.C. 348; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 355; 21 U.S.C. 360b; 21 U.S.C. 361; 21 U.S.C. 371; 21 U.S.C. 372; 21 U.S.C. 374; 15 U.S.C. 402; 15 U.S.C. 409

Abstract: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulation (21 CFR 2.125) on uses of ozone-depleting substances (ODSs), including chlorofluorocarbons (CFCs), to remove designations for certain products as essential uses under the Clean Air Act. Essential-use products are exempt from FDA's ban on the use of CFC propellants in FDA-regulated products and the Environmental Protection Agency's (EPA's) ban on the use of CFCs and other ODSs in pressurized dispensers. This action, if finalized, will remove essential use exemptions for sterile aerosol talc administered intrapleurally by thoracoscopy for human use, metered-dose atropine sulfate aerosol human drugs administered by oral inhalation, and anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application. FDA is proposing this action because alternative products that do not use ODSs are now available and because these products are no longer

being marketed in approved versions that contain ODSs. On June 29, 2015, FDA published a notice and request for comment concerning its tentative conclusion that these products are no longer an essential use under the Clean Air Act (80 FR 36937). The Agency received no comments concerning removal of essential use designations for sterile aerosol talc and metered-dose atropine sulfate, and is proposing to remove these designations by direct final rule and a companion proposed rule in the event adverse comments are received. FDA received one comment concerning removal of anesthetic drugs for topical use in response to its 2015 notice and request for comment, and is proposing to remove this exemption through a separate notice. Because these products are not currently sold in the approved form, no significant economic impact is anticipated.

Timetable:

Action	**Date**	**FR Cite**
NPRM	12/00/16	

Regulatory Flexibility Analysis Required: No

Agency Contact: Daniel Orr, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Building 51, Room 5199, 10993 New Hampshire Ave, Silver Spring, MD 20993

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RIN: 0910–AH36

Department of Health and Human Services (HHS)	**Final Rule Stage**

Food and Drug Administration (FDA)	

273. POSTMARKETING SAFETY REPORTING REQUIREMENTS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS

Legal Authority: 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 242a; 42 U.S.C. 262 and 263; 42 U.S.C. 263a to 263n; 42 U.S.C. 264; 42 U.S.C. 300aa; 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 360b to 360j; 21 U.S.C. 361a; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 375; 21 U.S.C. 379e; 21 U.S.C. 381

Abstract: The final rule would amend the postmarketing expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Council on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. Premarketing safety reporting requirements were finalized in a separate final rule published on September 29, 2010 (75 FR 59961). This final rule applies to postmarketing safety reporting requirements.

Timetable:

Action	Date	FR Cite
NPRM	03/14/03	68 FR 12406
NPRM Comment Period Extended	06/18/03	
NPRM Comment Period End	07/14/03	
NPRM Comment Period	10/14/03	

Extension End		
Final Action	08/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jane E. Baluss, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6278, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002

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RIN: 0910–AA97

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274. MEDICAL GAS CONTAINERS AND CLOSURES; CURRENT GOOD MANUFACTURING PRACTICE REQUIREMENTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 351 to 21 U.S.C. 353

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas accidents, do not occur in the future. FDA has described

a number of proposals in the proposed rule including requiring that gas use outlet connections on portable cryogenic medical gas containers be securely attached to the valve body.

Timetable:

Action	Date	FR Cite
NPRM	04/10/06	71 FR 18039
NPRM Comment Period End	07/10/06	
Final Action	11/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Patrick Raulerson, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 51, Room 6368, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002

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Email: patrick.raulerson@fda.hhs.gov

RIN: 0910–AC53

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275. HUMAN SUBJECT PROTECTION; ACCEPTANCE OF DATA FROM CLINICAL INVESTIGATIONS FOR MEDICAL DEVICES

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351; 21 U.S.C. 352; 21 U.S.C. 360; 21 U.S.C. 360c; 21 U.S.C. 360e; 21 U.S.C. 360i; 21 U.S.C. 360j; 21 U.S.C. 371; 21 U.S.C. 374; 21 U.S.C. 381; 21 U.S.C. 393; 42 U.S.C. 264; 42 U.S.C. 271; ...

Abstract: This rule will amend FDA's regulations on acceptance of data for medical devices to require that clinical investigations submitted in support of a research or marketing application submission be conducted in accordance with good clinical practice if conducted outside the United States and in accordance with FDA's regulations if conducted in the United States.

Timetable:

Action	Date	FR Cite
NPRM	02/25/13	78 FR 12664
NPRM Comment Period End	05/28/13	
Final Action	12/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Soma Kalb, Biomedical Engineer, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiologica Heath, Bldg 66 Room 1534, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG48

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276. SUPPLEMENTAL APPLICATIONS PROPOSING LABELING CHANGES FOR APPROVED DRUGS AND BIOLOGICAL PRODUCTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 352; 21 U.S.C. 353; 21 U.S.C. 355; 21 U.S.C. 371; 42 U.S.C. 262; ...

Abstract: This rule would amend the regulations regarding new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license application (BLAs) to revise and clarify procedures for changes to the labeling of an approved drug to reflect certain types of newly acquired information in advance of FDA's review of such change.

Timetable:

Action	Date	FR Cite
NPRM	11/13/13	78 FR 67985
NPRM Comment Period Extended	12/27/13	78 FR 78796
NPRM Comment Period End	01/13/14	
NPRM Comment Period Extended End	03/13/14	
NPRM Comment Period Reopened	02/18/15	80 FR 8577
NPRM Comment Period Reopened End	04/27/15	
Final Rule	04/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice L. Weiner, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 6268, 10903 New Hampshire Avenue, Silver Spring, MD 20993–0002

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Email: janice.weiner@fda.hhs.gov

RIN: 0910–AG94

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277. FOOD LABELING; GLUTEN–FREE LABELING OF FERMENTED, HYDROLYZED, OR DISTILLED FOODS

Legal Authority: sec 206 of the Food Allergen Labeling and Consumer Protection Act; 21 U.S.C. 343(a)(1); 21 U.S.C. 321(n); 21 U.S.C. 371(a)

Abstract: This proposed rule would establish requirements concerning compliance for using a "gluten-free" labeling claim for those foods for which there is no scientifically valid analytical method available that can reliably detect and accurately quantify the presence of 20 parts per million (ppm) gluten in the food.

Timetable:

Action	Date	FR Cite
NPRM	11/18/15	80 FR 71990
NPRM Comment Period Reopened	01/22/16	81 FR 3751
NPRM Comment Period End	02/16/16	
NPRM Comment Period Reopened	02/22/16	81 FR 8869
NPRM Comment Period Reopened End	04/25/16	

Final Action	04/00/17	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AH00

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278. GENERAL AND PLASTIC SURGERY DEVICES: SUNLAMP PRODUCTS

Legal Authority: 21 U.S.C. 360j(e)

Abstract: This rule would apply device restrictions to sunlamp products. The incidence of skin cancer, including melanoma, has been increasing, and a large number of skin cancer cases are attributable to the use of sunlamp products. The devices may cause about 400,000 cases of skin cancer per year, and 6,000 of which are melanoma. Beginning sunlamp product use at young ages, as well as frequently using sunlamp products, both increase the risk of developing skin cancers and other illnesses, and sustaining other injuries. Even infrequent use, particularly at younger ages, can significantly increase these risks.

Sunlamp products incorporate ultraviolet (UV) lamps and include devices such as UV tanning beds and booths. People who use sunlamp products are at increased risk of developing skin cancer and other illnesses, and sustaining injuries.

Timetable:

Action	Date	FR Cite
NPRM	12/22/15	80 FR 79493
NPRM Comment Period End	03/21/16	
Final Action	02/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ian Ostermiller, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Building 66 Room 5515, 10903 New Hampshire Avenue, Silver Spring, MD 20993

Phone: 301 796–5678

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RIN: 0910–AH14

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279. • SUBMISSION OF FOOD AND DRUG ADMINISTRATION IMPORT DATA IN THE AUTOMATED COMMERCIAL ENVIRONMENT (SECTION 610 REVIEW)

Legal Authority: Not Yet Determined

Abstract: The Food and Drug Administration (FDA, the Agency, or we) will establish requirements for the electronic filing of entries of FDA-regulated products in the Automated Commercial Environment (ACE) or any other electronic data interchange (EDI) system authorized by the U.S. Customs and Border Protection (CBP), in order for the filing to be processed by CBP and to help FDA in determining admissibility of that product.

Timetable:

Action	Date	FR Cite
ANPRM	07/01/16	81 FR 43155
ANPRM Comment Period End	08/30/16	
Final Rule	11/00/16	
Final Rule Effective	12/00/16	

Regulatory Flexibility Analysis Required: No

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RIN: 0910–AH41

Department of Health and Human Services (HHS)	Long-Term Actions
Food and Drug Administration (FDA)	

280. LASER PRODUCTS; AMENDMENT TO PERFORMANCE STANDARD

Legal Authority: 21 U.S.C. 360hh to 360ss; 21 U.S.C. 371; 21 U.S.C. 393

Abstract: FDA is proposing to amend the 2013 proposed rule for the performance standard for laser products, which will amend the performance standard for laser products to achieve closer harmonization between the current standard and the recently amended International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The amendment is intended to update FDA's performance standard to reflect advancements in technology.

Timetable:

Action	Date	FR Cite
NPRM	06/24/13	78 FR 37723
NPRM Comment Period End	09/23/13	
NPRM (Reproposal)	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Erica Blake–Payne, Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, WO 66, Room 4426, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AF87

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281. REQUIREMENTS FOR THE TESTING AND REPORTING OF TOBACCO PRODUCT CONSTITUENTS, INGREDIENTS, AND ADDITIVES

Legal Authority: 21 U.S.C. 301 et seq.; 21 U.S.C. 387; The Family Smoking Prevention and Tobacco Control Act

Abstract: The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, requires the Food and Drug Administration to promulgate regulations that require the testing and reporting of tobacco product constituents, ingredients, and additives, including smoke constituents, that the Agency determines should be tested to protect the public health.

Timetable:

Action	Date	FR Cite
NPRM	04/00/18	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Laura Rich, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Building 71, G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG59

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282. REGULATIONS ON HUMAN DRUG COMPOUNDING UNDER SECTIONS 503A AND 503B OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Legal Authority: 21 U.S.C. 353a; 21 U.S.C. 353b; 21 U.S.C. 371

Abstract: FDA will propose regulations to define and implement certain statutory conditions under which compounded products may qualify for exemptions from certain requirements.

Timetable:

Action	Date	FR Cite
NPRM	12/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Sara Rothman, Consumer Safety Officer, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Building 51, Room 5197, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH10

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283. • TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE: FINAL MONOGRAPH FOR CONSUMER ANTISEPTIC WASH PRODUCTS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360 to 361; 21 U.S.C. 371; 21 U.S.C. 374 to 375; 21 U.S.C. 379; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 262

Abstract:

This final rule amends the 1994 tentative final monograph (TFM) for over-the-counter (OTC) antiseptic drug products that published in the Federal Register of June 17, 1994 (the 1994 TFM).

The final rule is part of the ongoing review of OTC drug products conducted by FDA.

In this final rule, we address whether certain active ingredients used in OTC consumer antiseptic products intended for use with water (referred to as consumer antiseptic washes) are not generally recognized as safe and effective (GRAS/GRAE) and are misbranded.

Timetable:

Action	Date	FR Cite
NPRM	12/17/13	78 FR 764444
NPRM Comment Period End	06/16/14	
Final Action	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Pranvera Ikonomi, Biologist, Department of Health and Human Services, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AH40

Department of Health and Human Services (HHS)	Completed Actions
Food and Drug Administration (FDA)	

284. REQUIREMENTS FOR FOREIGN AND DOMESTIC ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN DRUGS, INCLUDING DRUGS THAT ARE REGULATED UNDER A BIOLOGICS LICENSE APPLICATION, AND ANIMAL DRUGS

Legal Authority: 21 U.S.C. 321 and 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355 to 356c; 21 U.S.C. 360 and 360b; 21 U.S.C. 360c to 360f; 21 U.S.C. 360h to 360j; 21 U.S.C. 371 and 374; 21 U.S.C. 379e and 381; 21 U.S.C. 393; 15 U.S.C. 1451 to 1561; 42 U.S.C. 262 and 264; 42 U.S.C. 271; and sec 122; Pub. L. 105–115, 11 Stat. 2322 (21 U.S.C. 355 note)

Abstract: The rule will reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, including certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted. They also address National Drug Codes.

Timetable:

Action	Date	FR Cite
NPRM	08/29/06	71 FR 51276
NPRM Comment Period End	02/26/07	
Final Action	08/31/16	81 FR 60170
Final Action Effective	11/29/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: David Joy, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Building 51, Room 6254, Silver Spring, MD 20993

Phone: 301 796–2242

Email: david.joy@fda.hhs.gov

RIN: 0910–AA49

285. FOOD LABELING: REVISION OF THE NUTRITION AND SUPPLEMENT FACTS LABELS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 343; 21 U.S.C. 371

Abstract: FDA is amending the labeling regulations for conventional foods and dietary supplements to provide updated nutrition information on the label to assist consumers in maintaining healthy dietary practices. The rule will modernize the nutrition information found on the Nutrition Facts label, as well as the format and appearance of the label. On July 27, 2015, FDA issued a supplemental notice of proposed rulemaking accepting comments on limited additional provisions until October 13, 2015. Also on July 27, 2015, FDA reopened the comment period on the proposed rule as to specific documents until September 25, 2015. In addition, in response to requests for the raw data related to FDA's consumer studies on the nutrition label, FDA issued a notice on September 10, 2015 to make the raw data available for comment until October 13, 2015 and extended the comment period for the July 27, 2015 reopening as to specific documents to October 13, 2015. On October 20, 2015, FDA extended the comment period for the consumer studies and the supplemental proposal to October 23, 2015.

Timetable:

Action	**Date**	**FR Cite**
ANPRM	07/11/03	68 FR 41507
ANPRM Comment Period End	10/09/03	
Second ANPRM	04/04/05	70 FR 17008
Second ANPRM Comment Period End	06/20/05	
Third ANPRM	11/02/07	72 FR 62149

Third ANPRM Comment Period End	01/31/08	
NPRM	03/03/14	79 FR 11879
NPRM Comment Period End	06/02/14	
Reopening of Comment Period as to Specific Documents	07/27/15	80 FR 44302
NPRM Comment Period End as to Specific Documents	09/25/15	
Supplemental NPRM to Solicit Comment on Limited Additional Provisions	07/27/15	80 FR 44303
Supplemental NPRM to Solicit Comment on Limited Additional Provisions Comment Period End	10/13/15	
Administrative Docket Update; Extension of Comment Period	09/10/15	80 FR 54446
Administrative Docket Update; Comment Period End	10/13/15	
NPRM Reopening of Comment Period for Certain	10/20/15	80 FR 63477

Documents		
NPRM Reopening of Comment Period for Certain Documents Comment Period End	10/23/15	
Final Action	05/27/16	81 FR 33741

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF22

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286. FOOD LABELING: SERVING SIZES OF FOODS THAT CAN REASONABLY BE CONSUMED AT ONE EATING OCCASION; DUAL–COLUMN LABELING; UPDATING, MODIFYING, AND ESTABLISHING CERTAIN RACCS

Legal Authority: 21 U.S.C. 321; 21 U.S.C. 343; 21 U.S.C. 371; Pub. L. 101–535, sec 2(b)(1)(A)

Abstract: FDA is amending its labeling regulations for foods to provide update, modify, and establish Reference Amounts Customarily Consumed (RACCs) for certain food categories. This rule would provide consumers with nutrition information based on the amount of food that is customarily consumed, which would assist consumers in maintaining healthy dietary practices. In addition to updating, modifying, and establishing certain RACCs, FDA is amending the definition of a single-serving containers; amending the

label serving size for breath mints; and providing for dual-column labeling under certain circumstances, which would provide nutrition information per serving and per container or unit, as applicable; and making technical amendments to various aspects of the serving size regulations.

Timetable:

Action	Date	FR Cite
ANPRM	04/04/05	70 FR 17010
ANPRM Comment Period End	06/20/05	
NPRM/Comment Period Extended	03/03/14	79 FR 11989
NPRM Comment Period End	06/02/14	
NPRM Comment Period Extended	05/27/14	79 FR 29699
NPRM Comment Period End	08/01/14	
Final Action	05/27/16	81 FR 34000

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF23

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287. SAFETY AND EFFECTIVENESS OF CONSUMER ANTISEPTICS; TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

Legal Authority: 21 U.S.C. 321p; 21 U.S.C. 331; 21 U.S.C. 351 to 353; 21 U.S.C. 355; 21 U.S.C. 360; 21 U.S.C. 371; 21 U.S.C. 361; 21 U.S.C. 374; 21 U.S.C 375; 21 U.S.C 379; 42 U.S.C. 216; 42 U.S.C. 241; 42 U.S.C. 242; 42 U.S.C. 262; ...

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective, and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antimicrobial agents in consumer antiseptic hand wash.

Timetable:

Action	Date	FR Cite
NPRM	06/17/94	59 FR 31402
Comment Period End	12/15/95	
NPRM (Consumer Hand Wash Products)	12/17/13	78 FR 76443
NPRM (Consumer Hand Wash) Comment Period End	06/16/14	
NPRM (Healthcare Antiseptic)	05/01/15	80 FR 25166

NPRM Comment Period End (Healthcare Antiseptic)	10/28/15	
NPRM (Consumer Hand Rub)	06/30/16	81 FR 42912
NPRM Comment Period End (Consumer Hand Rub)	12/27/16	
Final Rule	09/06/16	81 FR 61106
Final Rule Effective	09/06/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Janice Adams–King, Regulatory Health Project Manager, Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, WO 22, Room 5416, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AF69

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288. ABBREVIATED NEW DRUG APPLICATIONS AND 505(B)(2) APPLICATIONS

Legal Authority: Pub. L. 108–173, title XI; 21 U.S.C. 355; 21 U.S.C. 371

Abstract: This proposed rule would make changes to certain procedures for Abbreviated New Drug Applications and 505(b)(2) applications relating to patent certifications, notice to patent owners and application holders, the availability of a 30-month stay of approval, amendments and supplements, and the types of bioavailability and bioequivalence data that can be used to support these applications.

Timetable:

Action	Date	FR Cite
NPRM	02/06/15	80 FR 6802
NPRM Comment Period End	05/07/15	
NPRM Comment Period Extended	04/24/15	80 FR 22953
NPRM Comment Period Extended End	06/08/15	
Final Action	10/16/16	81 FR 69580
Final Action Effective	12/05/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0910–AF97

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289. "TOBACCO PRODUCTS" SUBJECT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

Legal Authority: 21 U.S.C. 301 et seq.; The Federal Food, Drug, and Cosmetic Act; Pub. L. 111–31; The Family Smoking Prevention and Tobacco Control Act

Abstract: The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) provides the Food and Drug Administration (FDA) authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, permits FDA to issue regulations deeming other tobacco products to be subject to the FD&C Act. This rule would deem additional products meeting the statutory definition of "tobacco product" to be subject to the FD&C Act, and would specify additional restrictions.

Timetable:

Action	Date	FR Cite
NPRM	04/25/14	79 FR 23142
NPRM Comment Period End	07/09/14	
NPRM Comment Period Extended	06/24/14	79 FR 35711
NPRM Comment Period Extended End	08/08/14	
Final Action	05/10/16	81 FR 28974

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Gerie Voss, Senior Regulatory Counsel, Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Room G335, 10903 New Hampshire Avenue, Silver Spring, MD 20993

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RIN: 0910–AG38

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290. FOCUSED MITIGATION STRATEGIES TO PROTECT FOOD AGAINST INTENTIONAL ADULTERATION

Legal Authority: 21 U.S.C. 331; 21 U.S.C. 342; 21 U.S.C. 350g; 21 U.S.C. 350i; 21 U.S.C. 371; 21 U.S.C. 374; Pub. L. 111–353

Abstract: This rule would require domestic and foreign food facilities that are required to register under the Federal Food, Drug, and Cosmetic Act to address hazards that may be intentionally introduced by acts of terrorism. These food facilities would be required to identify and implement focused mitigation strategies to significantly minimize or prevent significant vulnerabilities identified at actionable process steps in a food operation.

Timetable:

Action	Date	FR Cite
NPRM	12/24/13	78 FR 78014
NPRM Comment Period Extended	03/25/14	79 FR 16251
NPRM Comment Period End	03/31/14	
NPRM Comment Period Extended End	06/30/14	

Final Rule	05/27/16	81 FR 34166

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Jody Menikheim, Supervisory General Health Scientist, Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–005), 5100 Paint Branch Parkway, College Park, MD 20740

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RIN: 0910–AG63

Department of Health and Human Services (HHS)	**Proposed Rule Stage**
Centers for Medicare & Medicaid Services (CMS)	

291. • HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR ACUTE CARE HOSPITALS AND THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FY 2018 RATES (CMS–1677–P) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems.

Timetable:

Action	Date	FR Cite
NPRM	04/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Donald Thompson, Deputy Director, Division of Acute Care, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–26, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS98

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292. • CY 2018 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1676–P) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract: This annual proposed rule would revise payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes would apply to services furnished beginning January 1, 2018.

Timetable:

Action	Date	FR Cite
NPRM	06/00/17	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ryan Howe, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AT02

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293. • CY 2018 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1678–P) (SECTION 610 REVIEW)

Regulatory Plan: This entry is Seq. No. 46 in part II of this issue of the **Federal Register.**

RIN: 0938–AT03

Department of Health and Human Services (HHS)	**Final Rule Stage**
Centers for Medicare & Medicaid Services (CMS)	

294. MERIT–BASED INCENTIVE PAYMENT SYSTEM (MIPS) AND ALTERNATIVE PAYMENT MODELS (APMS) IN MEDICARE FEE–FOR–SERVICE (CMS–5517–FC) (SECTION 610 REVIEW)

Legal Authority: Pub. L. 114–10, sec 101

Abstract: This rule implements provisions of the Medicare Access and CHIP Reauthorization Act (MACRA) related to MIPS and APMs. Section 101 of MACRA authorizes a new MIPS, which repeals the Medicare sustainable growth rate and improves Medicare payments for physician services. MACRA consolidates the current programs of the Physician Quality Reporting System, the Value-Based Modifier, and the Electronic Health Records Incentive Program into one program, MIPS, that streamlines and improves on the three distinct incentive programs. Additionally, MACRA authorizes incentive payments for providers who participate in eligible APMs.

Timetable:

Action	Date	FR Cite
NPRM	05/09/16	81 FR 28161
NPRM Comment Period End	06/27/16	
Final Action	11/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: James Sharp, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare & Medicaid Innovation Center, MS: WB–06–05, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS69

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295. CY 2017 HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE; HOME HEALTH VALUE–BASED PURCHASING MODEL; AND HOME HEALTH QUALITY REPORTING REQUIREMENTS (CMS–1648–F) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract:

This annual rule updates the 60-day national episode rate, the national per-visit rates used to calculate low utilization payment adjustments (LUPAs), and outlier payments under the Medicare prospective payment system for home health agencies. The rule also updates the provisions of the Home Health Value-Based Purchasing (HHVBP) program.

Timetable:

Action	Date	FR Cite
NPRM	07/05/16	81 FR 43714
NPRM Comment Period End	08/26/16	
Final Action	11/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Hillary Loeffler, Director, Division of Home Health and Hospice, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C5–07–22, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS80

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296. CY 2017 REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER REVISIONS TO MEDICARE PART B (CMS–1654–F) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh; Pub. L. 114–10

Abstract:

This annual rule revises payment polices under the Medicare physician fee schedule, and make other policy changes to payment under Medicare Part B. These changes apply to services furnished beginning January 1, 2017.

Timetable:

Action	Date	FR Cite
NPRM	07/15/16	81 FR 46162
NPRM Comment Period End	09/06/16	
Final Action	11/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Ryan Howe, Director, Division of Practitioner Services, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–01–15, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS81

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297. CY 2017 HOSPITAL OUTPATIENT PPS POLICY CHANGES AND PAYMENT RATES AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEM POLICY CHANGES AND PAYMENT RATES (CMS–1656–FC) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract:

This annual rule revises the Medicare hospital outpatient prospective payment system to implement statutory requirements and changes arising from our continuing experience with this system. The rule describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule changes the ambulatory surgical center payment system list of services and rates.

Timetable:

Action	Date	FR Cite
NPRM	07/14/16	81 FR 45604
NPRM Comment Period End	09/06/16	
Final Action	11/00/16	

Regulatory Flexibility Analysis Required: Yes

Agency Contact: Marjorie Baldo, Health Insurance Specialist, Department of Health and Human Services, Centers for Medicare & Medicaid Services, Center for Medicare, MS: C4–03–06, 7500 Security Boulevard, Baltimore, MD 21244

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RIN: 0938–AS82

Department of Health and Human Services (HHS)	Long-Term Actions
Centers for Medicare & Medicaid Services (CMS)	

298. CONDITIONS OF PARTICIPATION FOR HOME HEALTH AGENCIES (CMS–3819–F)

(RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395x; 42 U.S.C. 1395cc(a); 42 U.S.C. 1395hh; 42 U.S.C. 1395bb

Abstract: This final rule revises the conditions of participation (CoPs) that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	03/10/97	62 FR 11005
NPRM Comment Period End	06/09/97	
Second NPRM	10/09/14	79 FR 61163
NPRM Comment Period Extended	12/01/14	79 FR 71081

NPRM Comment Period End	12/08/14	
NPRM Comment Period Extended End	01/07/15	
Final Action	10/00/17	

Regulatory Flexibility Analysis Required: No

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RIN: 0938–AG81

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299. HOSPITAL AND CRITICAL ACCESS HOSPITAL (CAH) CHANGES TO PROMOTE INNOVATION, FLEXIBILITY, AND IMPROVEMENT IN PATIENT CARE (CMS–3295–F) (RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh and 1395rr

Abstract: These proposed changes would modernize hospital and critical access hospital (CAH) requirements, improve quality of care, and support HHS and CMS priorities. Specifically, we proposed to revise the conditions of participation (CoPs) for hospitals and CAHs to address: Discriminatory behavior by healthcare providers that may create real or perceived barriers to care; Use of the term "Licensed Independent Practioners" (LIPs) that may inadvertently exacerbate workforce shortage concerns; Requirements that do not fully conform to current standards for infection control; Requirements for antibiotic stewardship programs to help reduce inappropriate antibiotic use and antimicrobial resistance;

and the use of quality reporting program data by hospital Quality Assessment and Performance Improvement (QAPI) programs.

Timetable:

Action	Date	FR Cite
NPRM	06/16/16	81 FR 39447
NPRM Comment Period End	08/15/16	
Final Action	06/00/19	

Regulatory Flexibility Analysis Required: No

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RIN: 0938–AS21

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300. IMAGING ACCREDITATION (CMS–3309–P) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1395hh; 42 U.S.C. 1102

Abstract: This proposed rule would establish standards for Imaging Accreditation. These proposed standards would address qualifications for clinical personnel, standards to ensure that suppliers have established policies and procedures governing the use of equipment in furnishing the technical component of advanced diagnostic imaging, and the establishment and maintenance of a quality assurance and quality control program to ensure reliability, clarity, and accuracy of the diagnostic images.

Timetable:

Action	Date	FR Cite
NPRM	To Be	Determined

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS62

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301. PART B DRUG PAYMENT MODEL (CMS–1670–F) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302, 1315(a), and 1395hh

Abstract: This final rule implements the Part B Drug Payment Model, which is a two-phase model that tests whether alternative drug payment designs will lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries.

Timetable:

Action	Date	FR Cite
NPRM	03/11/16	81 FR 13229
NPRM Comment Period End	05/09/16	

Final Action	03/00/19	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS85

Department of Health and Human Services (HHS)	**Completed Actions**
Centers for Medicare & Medicaid Services (CMS)	

302. EMERGENCY PREPAREDNESS REQUIREMENTS FOR MEDICARE AND MEDICAID PARTICIPATING PROVIDERS AND SUPPLIERS (CMS–3178–F) (SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1821; 42 U.S.C. 1861ff (3)(B)(i)(ii); 42 U.S.C. 1913(c)(1) et al

Abstract: This rule finalizes emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to ensure that they adequately plan for both natural and man-made disasters and coordinate with Federal, State, tribal, regional, and local emergency preparedness systems. This rule ensures providers and suppliers are adequately prepared to meet the needs of patients, residents, clients, and participants during disasters and emergency situations.

Timetable:

Action	Date	FR Cite
NPRM	12/27/13	78 FR 79082
NPRM Comment Period Extended	02/21/14	79 FR 9872
NPRM Comment Period End	02/25/14	
NPRM Comment Period Extended End	03/31/14	
Final Action	09/16/16	81 FR 63859
Final Action Effective	11/15/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AO91

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303. REFORM OF REQUIREMENTS FOR LONG–TERM CARE FACILITIES (CMS–3260–F)

(RULEMAKING RESULTING FROM A SECTION 610 REVIEW)

Legal Authority: Pub. L. 111–148, sec 6102; 42 U.S.C. 263a; 42 U.S.C. 1302; 42 U.S.C. 1395hh; 42 U.S.C. 1395rr

Abstract: This final rule revises the requirements that long-term care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety. The revisions are an integral part of our efforts to achieve broad-based improvements both in the quality of health care furnished through federal programs, and in patient safety, while at the same time reducing procedural burdens on providers.

Timetable:

Action	Date	FR Cite
NPRM	07/16/15	80 FR 42167
NPRM Comment Period Extension	09/15/15	80 FR 55284
NPRM Comment Period End	09/14/15	
NPRM Comment Period Extended End	10/14/15	
Final Action	10/04/16	81 FR 68688
Final Action Effective	11/28/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AR61

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304. MEDICARE CLINICAL DIAGNOSTIC LABORATORY TEST PAYMENT SYSTEM (CMS–1621–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Pub. L. 113–93, sec 216

Abstract: This final rule revises the Medicare payment system for clinical diagnostic laboratory tests and implements other changes required by section 216 of the Protecting Access to Medicare Act of 2014.

Timetable:

Action	Date	FR Cite
NPRM	10/01/15	80 FR 59385
NPRM Comment Period End	11/25/15	
Final Action	06/23/16	81 FR 41036
Final Action Effective	08/22/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS33

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305. MEDICARE SHARED SAVINGS PROGRAM; ACCOUNTABLE CARE ORGANIZATIONS (ACOS)—REVISED BENCHMARK REBASING METHODOLOGY (CMS–1644–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: Pub. L. 111–148 sec. 3022

Abstract: Under the Medicare Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare fee-for-service (FFS) payments under parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements. This rule addresses changes to the Shared Savings Program that modify the program's benchmark rebasing methodology to encourage ACOs' continued investment in care coordination and quality improvement, and identifies publicly available data to support modeling and analysis of these changes. In addition, it streamlines the methodology used to adjust an ACO's historical benchmark for changes in its ACO participant composition, offers an alternative participation option to encourage ACOs to enter performance-based risk arrangements earlier in their participation under the program, and establishes policies for reopening of payment determinations to make corrections after financial calculations have been performed and ACO shared savings and shared losses for a performance year have been determined.

Timetable:

Action	Date	FR Cite
NPRM	02/03/16	81 FR 5823
NPRM Comment Period End	03/28/16	
Final Action	06/10/16	81 FR 37950
Final Action Effective	08/09/16	

Regulatory Flexibility Analysis Required: Yes

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RIN: 0938–AS67

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306. HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM FOR ACUTE CARE HOSPITALS AND THE LONG–TERM CARE HOSPITAL PROSPECTIVE PAYMENT SYSTEM AND FY 2017 RATES (CMS–1655–F) (COMPLETION OF A SECTION 610 REVIEW)

Legal Authority: 42 U.S.C. 1302; 42 U.S.C. 1395hh

Abstract:

This annual final rule revises the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This rule implements changes arising from our continuing experience with these systems.

Timetable:

Action	Date	FR Cite
NPRM	04/27/16	81 FR 24946
NPRM Comment Period End	06/17/16	
Final Action	08/22/16	81 FR 56762
Final Action Effective	10/01/16	

Regulatory Flexibility Analysis Required: Yes

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